CLAIMS

What is claimed:

1. A method of treating breast cancer which comprises administering, to a subject suffering from breast cancer,

a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and

a second amount of an immunological agent, effective to contribute to the development of a protective immune response to said breast cancer,

where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers.

2. The method of claim 1 where said agents are administered concurrently.

3. The method of claims 1 or 2 where said immunological agent comprises at least one immunogen, said immunogen comprising at least one breast cancer-associated epitope.

4. The method of claim 3 where at least one epitope is a MUC1 epitope.

5. The method of claim 3 where at least one epitope is a carbohydrate epitope.

6. The method of claim 3 in which said immunogen comprises STn.

7. The method of claim 6 in which said immunogen comprising STn is an STn-KLH conjugate.

8. The method of claim 7 in which the conjugate is an aggregated conjugate.

9. The method of claim 7 or 8 in which the conjugate has a NANA content of about 7%.

10. The method of any one of claims 1-9 in which the anti-estrogenic steroid agent comprises at least one antiestrogen.

11. The method of claim 10 in which at least one antiestrogen is a steroidal antiestrogen.

12. The method of claim 1 in which at least one anti-estrogenic steroid agent is fulvestrant.

13. The method of claim 10 in which at least one antiestrogen is a nonsteroidal antiestrogen.

14. The method of claim 13 in which at least one nonsteroidal antiestrogen is selected from the group consisting of toremifene, tamoxifen, droloxifene and trioxifene

15. The method of any one of claims 1-14 in which the anti-estrogenic steroid agent comprises at least one aromatase inhibitor.

16. The method of claim 15 in which at least one aromatase inhibitor is selected from the group consisting of aminoglutethimide, anastrozole, vorozole, letrozole, liarozole, megastrole, exemestane and formestane.

17. The method of any one of claims 1-16, further comprising administration of at least one progestin which protects against breast cancer.

18. The method of claim 17 in which at least one progestin is progesterone.

19. The method of any one of claims 1-18, further comprising administration of at least one anti-progestin which protects against breast cancer.

20. The method of any one of claims 1-19 in which the anti-estrogenic steroid agent comprises geoselin acetate or megestrol acetate.

21. The method of any one of claims 1-20 in which the combination of the anti-estrogenic steroid agent and the immunological agent is synergistically effective against breast cancer.

22. The method of any one of claims 1-21, further comprising administration of a therapeutically effective amount of at least one chemotherapeutic agent other than an anti-estrogenic steroid agent.

23. The method of claim 22 in which at least one chemotherapeutic agent is an anthracycline.

24. The method of claim 23 in which at least one anthracycline is selected from the group consisting of doxorubicin, daunorubicin, epirubicin, and idarubicin.

25. The method of claim 22 in which at least one chemotherapeutic agent is a taxane.

26. The method of claim 25 in which at least one taxane is paclitaxel or docetaxel.

27. The method of any one of claims 1-26 in which the anti-estrogenic steroid agent comprises at least one compound which antagonizes at least one estrogen receptor by competitively inhibiting the binding of an estrogen to that receptor without itself activating that receptor.

28. The method of claim 27 in which said receptor antagonist is not an agonist for any estrogen receptor.

29. The method of claim 27 in which said receptor inhibitor is also an agonist of at least one other estrogen receptor, and consequently is a SERM.

30. The method of claim 29 in which said SERM is selected from the group consisting of tamoxifen, toremifene,

droloxifen, clomifene, arzoxifene, raloxifene, LY 117018 and SERM EM-652.

31. The method of any one of claims 1-30 in which the breast cancer is a metastatic breast cancer.

32. A therapeutic composition comprising (a) at least one anti-estrogenic steroid agent, and (b) at least one immunogenic agent, which, when administered according to a suitable therapeutic schedule, is therapeutically effective against breast cancer.

33. A kit comprising a first container comprising at least one dose of at least one anti-estrogenic steroid agent, and a second container comprising at least one dose of at least one immunogenic agent, where said agents are, at least in combination, therapeutically effective against breast cancer.

34. Use of (1) a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and (2) a second amount of an immunological agent, effective to contribute to the development of a protective immune response to breast cancer,

where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers,

in the manufacture of one or more compositions for the treatment of breast cancer.

35. Use of an immunological agent, effective to contribute to the development of a protective immune response to breast cancer, in a manufacture of a composition for the treatment of breast cancer in a subject who is receiving or has received treatment with an anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject.

36. Use of an anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, in the manufacture of a composition for the treatment of breast cancer in a subject who is receiving or has received treatment with an immunological agent, effective to contribute to the development of a protective immune response to said breast cancer.

37. The use of claim 34, where the agent is or agents are as set forth in any of claims 2-30.

38. The composition of claim 32, wherein the agent is or agents are as set forth in any of claims 2-30.

39. The kit of claim 33, wherein the agent is or agents are as set forth in any of claims 2-30.